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(54) **Implantable heart defibrillator**

(57) An implantable heart defibrillator contains a pulse generator (2), controlled by a control unit (8), for emitting a plurality of heart stimulation pulses at a rate of several Hertz or more. The control unit is arranged to cause the pulse generator to emit heart stimulation pulses

with an energy content of the same, or somewhat greater, magnitude than conventional pacemaker pulses for a period of time long enough for the entire heart (6) to become refractory.

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Description

The present invention relates to an implantable heart defibrillator containing a pulse generator, controlled by a control unit, for emitting a plurality of heart stimulation pulses at a rate of several Hertz or more.

It is known that cardiac fibrillation can be triggered by a low-tension alternating current applied between the tip of an ordinary, implanted pacemaker electrode and an indifferent electrode in the body, e.g. the pacemaker enclosure. Thus, atrial fibrillation can be triggered by an alternating current, with a peak-to-peak amplitude of 18 V, applied via a 2 kohm series resistance to an electrode in the atrium. Here, a lower series resistance could trigger ventricular fibrillation. Ventricular fibrillation can otherwise be induced by an alternating current with an amplitude of e.g. 18 volts peak-to-peak, applied, via a 0.5 kohm series resistance, to an electrode in the ventricle. For fibrillation to be induced, the alternating current must be applied for a number of time periods lasting 1 to 2 s with inter-period intervals of the same duration.

Once fibrillation has been triggered, it can, as is known, be terminated with a defibrillator supplying a brief, powerful discharge pulse with a voltage on the order of 1,000 V and an energy content of 4 to 40 J. When defibrillation is successful, i.e. fibrillation is terminated, the heart can then immediately resume normal rhythm, indicating that an optimum energy level was selected for the defibrillation pulse, e.g. 40 J applied externally. Or cardiac arrest could occur, indicating that more energy, e.g. 120 J applied externally, was used than was needed for restoration of normal heart rhythm. In the latter instance, additional defibrillation must be considered. However, the heart can often be induced to resume normal rhythm if subjected to conventional pacemaker stimulation at e.g. 70/min. In order to achieve the most rapid possible recovery of the heart, this stimulation should be terminated as soon as sinus rhythm is detected. Recovery is then very rapid, and the heart normally returns to its normal state after about 10 minutes.

The above-described mechanism for triggering heart fibrillation with the aid of a low-tension alternating current can also be used for terminating fibrillation. One example hereof is the external AC defibrillators employed during the defibrillator's infancy. They employed an alternating current with several hundred volts and a frequency of 50-60 Hz. See Paul J. Troop, "Implantable Cardioverters and Defibrillators", Current problems in Cardiology, Volume XIV, No. 12, December 1989, pp.729-731.

EP-A1-0 588 127 describes an implantable heart defibrillator which utilizes the heart's anisotropic properties for making cells with a certain direction refractory by means of preparatory, relatively low-energy pulses. Fibrillation can then be stopped with a subsequent defibrillation shock with less energy than would be required in conventional defibrillation. Defibrillation can sometimes be achieved solely with the preparatory, low-energy pulses

without any subsequent defibrillation pulse. These preparatory, low-energy pulses are emitted for a period of time lasting from 10 ms up to the duration of a refractory period.

EP-A1-0 588 125 describes heart defibrillation with the aid of defibrillation sequences, consisting of low-energy stimulation pulses, and with conventional defibrillation shocks. The low-energy stimulation pulses cause defibrillation of parts of the heart, mainly those around the electrode used, whereas conventional defibrillation shocks are required to defibrillate the rest of the heart. The amplitude and duration of the low-energy stimulation pulses used greatly exceed pacemaker pulses.

The object of the present invention is to achieve an implantable defibrillator which makes defibrillation possible using much less energy than is possible in the prior art.

This object is achieved with a defibrillator of the kind described in the preamble and with the features set forth in patent claim 1.

In defibrillation according to the invention, the heart is thus converted from a state of fibrillation, in which more or less chaotic conditions prevail in the different parts of the heart, to a known state, resembling cardiac arrest, from which the heart can spontaneously resume its normal state or be stimulated into assuming its normal state. Since the heart stimulation pulses used have an energy content of the same, or somewhat greater, magnitude than those emitted by ordinary pacemakers, total energy consumption for a heart defibrillation is considerably less than has hitherto been required.

According to one advantageous embodiment of the defibrillator according to the invention, the control unit is arranged to cause the pulse generator to emit stimulation pulses for a period of one or several seconds so the entire heart becomes refractory.

According to another embodiment of the defibrillator according to the invention, the control unit is arranged to reduce the pulse generator's pulse rate to a normal pacing rate after the said period of time. This ensures that the heart reverts to its normal state after defibrillation. It may be appropriate for the normal heart rate to be achieved after a period lasting several seconds. This reduction in rate can advantageously be performed according to an appropriate, continuous curve as set forth in patent claims 6 and 7.

According to other advantageous embodiments of the defibrillator according to the invention, the pulse generator can be arranged to emit monophasic or biphasic pulses. The monophasic pulses can consist of half-periods of sinusoidal voltage, and the biphasic pulses can consist of whole-period sinusoidal voltage, thereby simplifying the pulse generator's design. Here, the sinusoidal oscillation's period must be brief, compared to the duration of the refractory period.

According to another advantageous embodiment of the defibrillator according to the invention, a detector is arranged to locally detect when heart cells leave the re-

fractory state, and the control device is arranged to cause the pulse generator to emit a stimulation pulse immediately thereafter. The detector can advantageously be arranged to locally detect the end of the T wave. Each stimulation pulse then captures a small area around the electrode or electrodes, and the area becomes refractory. Cells closest to the electrodes will then be the first ones to leave the refractory state. A new stimulation then follows, whereupon all the old area plus a number of non-refractory cells outside this area are captured and made refractory. This procedure is repeated, more and more cells then being captured and made refractory, so the entire heart, or a large part thereof, becomes refractory after a sufficient number of stimulation pulses. In this embodiment, the stimulation interval has essentially the same duration as the refractory period, i.e. about 150 ms.

The detector can advantageously be connected to a bipolar electrode with a small distance between the poles. This would make local detection possible without any serious noise interference from the surroundings.

According to another advantageous embodiment of the defibrillator according to the invention, the pulse generator is arranged to emit stimulation pulses to the heart across an electrode for pacemaker stimulation. Alternately, a plurality of variously sited electrode systems can be arranged for transmitting stimulation pulses, an electrode switching unit then being provided to connect the different electrode systems to the pulse generator for pulse emission according to a defined pattern. In this way, the distribution of current can be varied throughout the heart, so the heart is made refractory more effectively, and more efficient defibrillation of the heart is achieved.

According to an additional advantageous embodiment of the defibrillator according to the invention, the pulse generator is first made to emit a low-energy defibrillation or cardioversion pulse with several joules of energy before emission of heart stimulation pulses, at a rate of several Hertz or more, starts. Thus, treatment commences with a small shock-cardioversion, to ensure that a sufficiently large refractory "starting" area is created around the electrode, before treatment continues with the said heart stimulation pulses emitted at a rate of several Hertz or more.

The invention will now be described in greater detail with the aid of embodiments, referring to attached drawings in which

FIG. 1 is a block diagram of one embodiment of the defibrillator according to the invention;

FIGS. 2 and 3 show examples of continuous frequency control for the emission of stimulation pulses by the defibrillator according to the invention;

FIG. 4 shows an example of one way this frequency control can be achieved.

In the embodiment shown in FIG. 1, a pulse generator 2, via an electrode cable 4, and electrodes are connected to a heart 6 for supplying stimulation pulses to it. The pulse generator 2 is controlled by a control unit 8. A detector 10 is arranged to sense heart activity, via the electrode cable 4, and send detected information to the control unit 8 for controlling the pulse generator 2 in accordance therewith. An electrode switching unit 12 is devised to connect different electrode systems placed in the heart to the pulse generator 2 according to a defined pattern or in some optional way.

The defibrillator shown in FIG. 1 can be operated in the following manner.

Stimulation pulses are emitted by the pulse generator 2 each time heart cells locally leave their refractory state. The detector 10 detects when heart cells locally leave the refractory state in the fibrillating heart 6 by detecting the end of the T wave, whereupon this information is sent to the control unit 8 which causes the pulse generator to immediately emit a new stimulation pulse. For this detection, the detector 10 is connected to a bipolar electrode (not shown), with the electrode poles very close to each other, in the heart 6. This therefore makes possible local measurement of conditions between the electrode poles with minimum noise interference from the surroundings. The electrode can e.g. have a tip-ring configuration with the ring arranged at a very small distance from the tip.

After a stimulation pulse, the cells closest to the electrodes leave their refractory state first, whereupon a new stimulation pulse is emitted which accordingly converts all the "old" area of the heart, plus a number of additional non-refractory cells outside this area, to the refractory state. This procedure is repeated so increasing numbers of heart cells are captured in a "synchronized" area. This converts the entire heart to the refractory state after a sufficient number of stimulation pulses.

The duration of the refractory state is 150 to 250 ms. The stimulation rate is therefore on the order of 5 Hz.

After the entire heart has become refractory, the stimulation rate can be slowly reduced, allowing the heart to resume a normal operating rhythm in the normal way. Alternately, the heart can be stimulated at a normal pacemaker rate of, typically, 70/min. In order to achieve the fastest possible recovery of the heart, stimulation in the latter instance should be terminated as soon as sinus rhythm is detected.

Having a plurality of differently sited electrode systems, connected in an optional manner or according to a defined pattern with the electrode switching unit 12, in the heart may be advantageous. Here, an electrode should be located in the vicinity of the bundle of His, since depolarization waves propagated on normal signal pathways from the A-V node move more rapidly than other waves.

It is also possible to first create a refractory "starting" area in the heart by emitting a low-energy defibrillation pulse or cardioversion pulse of several joules and then

switching to the above-described defibrillation method.

The defibrillator according to the invention can obviously be used without this ability to switch between variously sited electrode systems, and a conventional pacemaker electrode, appropriately placed in the ventricle, can advantageously be used. However, the invention can also be employed for terminating atrial fibrillation.

One alternative way of operating the defibrillator according to the invention is to start with a fast stimulation rate, much faster than the fibrillation rate which normally amounts to about 300/min, i.e. the corresponding period is about as long as the refractory period of the heart cells.

The defibrillator can therefore be made to first emit a series of stimulation pulses at a fast rate, e.g. 50 Hz. The pulses can be monophasic or biphasic, and the amplitude can be e.g. 20 V. The pulses can consist of a half period (monophasic) or a whole period (biphasic) with a 50 Hz alternating current. This sequence of high-frequency stimulation pulses can be sent by the pulse generator 2 to the heart over a defined period of time. The intention here is to make the entire heart refractory.

After this high-frequency period, there is a change to a normal stimulation phase achieved by a rapid reduction in the rate at which pulses are emitted by the pulse generator 2 to a normal stimulation rate. The amplitude of the pulses can simultaneously be reduced to a normal pacemaker level of about 5 V. Controlling the pulse generator 2 in such a way that this normal level is reached several seconds after the high-frequency phase starts may be appropriate.

The pulse generator can be controlled so the rate for the pulses varies according to a semi-Gaussian curve, i.e.

$$f = f_0 * k_1 * e^{-k_2 * t^2}$$

in which f designates the frequency, f_0 designates the starting rate, e.g. 50 Hz, k_1 and k_2 designate constants and t designates the time.

One such frequency variation over time is shown in FIG. 2.

Alternately, frequency control can be according to a higher order exponential equation, i.e.

$$f = f_0 * k_1 * e^{-k_2 * t^4}$$

as illustrated in FIG. 3, if a faster drop in rate is desired after the high-frequency phase.

FIG. 4 shows how frequency control of the kind illustrated in FIGS. 2 and 3 can be achieved.

When the count-down timer 14 passes zero, which is detected with the zero detector 16, the address counter 18 increases one step, and the next period duration is downloaded from the period table 20 to the counter's 14 start register 22. At the same time, a triggering pulse is sent to the pulse generator 24 for emission of a stimulation pulse to the heart through the electrode cable. A new count-down phase then starts. When the count-down timer 14 again reaches zero, the process is repeated with downloading of the next period duration

etc.

The construction shown in FIG. 4 also contains a clock for controlling the count-down counter 14 and the requisite logic, block 26.

The pulse generator 24 is naturally also devised so the amplitude of output pulses can be controlled.

In this version of the defibrillator according to the invention, this frequency control is contained in the control unit 8 shown in the block diagram in FIG. 1. Since no detection of the refractory period takes place in this embodiment, the detector 10 has been omitted here.

Reference list

- 2 Pulse generator
- 4 Electrode cable
- 6 Heart
- 8 Control unit
- 10 Detector
- 12 Electrode switching unit
- 14 Count-down timer
- 16 Zero detector
- 18 Address counter
- 20 Period timetable
- 22 Start register
- 24 Pulse generator
- 26 Clock, logic

Claims

1. An implantable heart defibrillator containing a pulse generator (2), controlled by a control unit (8), for emitting a plurality of heart stimulation pulses at a rate of several Hertz or more, characterized in that the control unit (8) is devised to cause the pulse generator (2) to emit stimulation pulses with an energy content of the same, or somewhat greater, magnitude than conventional pacemaker pulses for a period of time long enough for the entire heart (6) to become refractory.
2. A defibrillator according to claim 1, characterized in that the control unit (8) is devised to cause the pulse generator (2) to emit heart stimulation pulses at a rate on the order of 10 Hz.

3. A defibrillator according to claim 1 or 2, characterized in that the control unit (8) is arranged to cause the pulse generator (2) to emit stimulation pulses for period of time lasting one or several seconds.
4. A defibrillator according to claim 1, characterized in that the control unit (8) is arranged to continuously reduce the rate of pulses from the pulse generator (2) from a rate faster than the heart fibrillation rate to a rate at which the entire heart (6) becomes refractory.
5. A defibrillator according to claims 3 or 4, characterized in that the control unit (8) is arranged to reduce the rate of pulses from the pulse generator (2) to a normal pacing rate after the said period of time.
6. A defibrillator according to claim 4 or 5, characterized in that the control unit (8) is arranged to continuously reduce the pulse generator's (2) rate according to a defined function.
7. A defibrillator according to claim 6, characterized in that the said defined function is a Gaussian function.
8. A defibrillator according to any of claims 4 to 6, characterized in that the control unit (8) is arranged to continuously reduce the pulse generator's (2) rate after the said period of time according to a higher order exponential curve.
9. A defibrillator according to any of claims 1 to 8, characterized in that the control unit (8) is arranged to cause the pulse generator (2) to emit pulses with a voltage amounting to several times the voltage of normal pacing pulses.
10. A defibrillator according to any of claims 1 to 9, characterized in that the pulse generator (2) is arranged to emit monophasic pulses.
11. A defibrillator according to claim 10, characterized in that the pulses consist of half-periods of high-frequency sinusoidal voltage.
12. A defibrillator according to any of claims 1 to 9, characterized in that the pulse generator (2) is arranged to emit biphasic pulses.
13. A defibrillator according to claim 12, characterized in that a biphasic pulse complex consists of one period of high-frequency sinusoidal voltage.
14. A defibrillator according to claim 1, characterized in that a detector (10) is arranged to locally detect when heart cells leave the refractory state, and the control unit (8) is arranged to cause the pulse generator (2) to emit a stimulation pulse immediately thereafter.
15. A defibrillator according to claim 14, characterized in that the detector (10) is arranged to locally detect the end of the T wave.
16. A defibrillator according to claim 14 or 15, characterized in that the detector (10) is connected to a bipolar electrode with a small distance between the poles.
17. A defibrillator according to any of claims 1 to 16, characterized in that the pulse generator (2) is arranged to emit stimulation pulses to the heart over an electrode for pacemaker stimulation.
18. A defibrillator according to any of claims 1 to 17, in which a plurality of differently sited electrode systems are arranged for transmitting stimulation pulses, characterized in that an electrode switching unit (12) is arranged to connect the different electrode systems to the pulse generator (2) for pulse emission according to a defined pattern.
19. A defibrillator according to any of claims 1 to 18, characterized in that the pulse generator (2) is controlled to first emit a low-energy defibrillation or cardioversion pulse with several joules of energy before emission of said heart stimulation pulses starts at a rate of several Hertz or more.

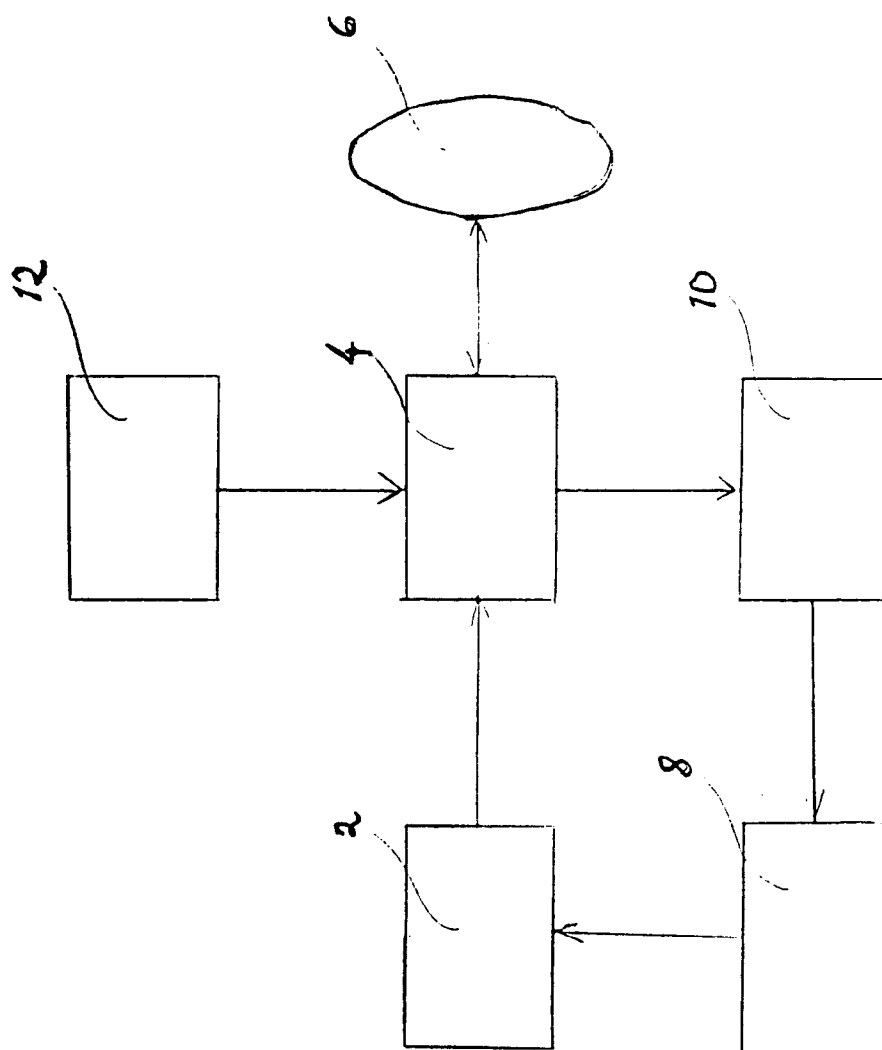


FIG 1

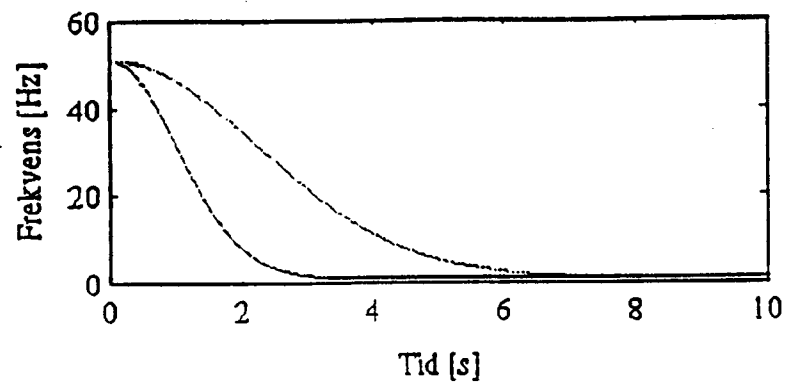


FIG 2

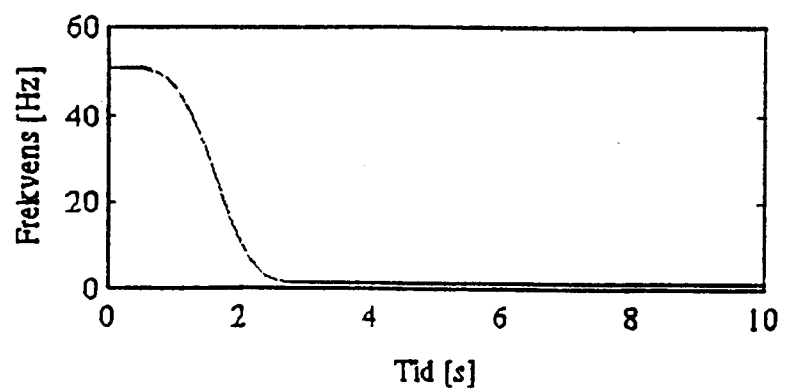


FIG 3

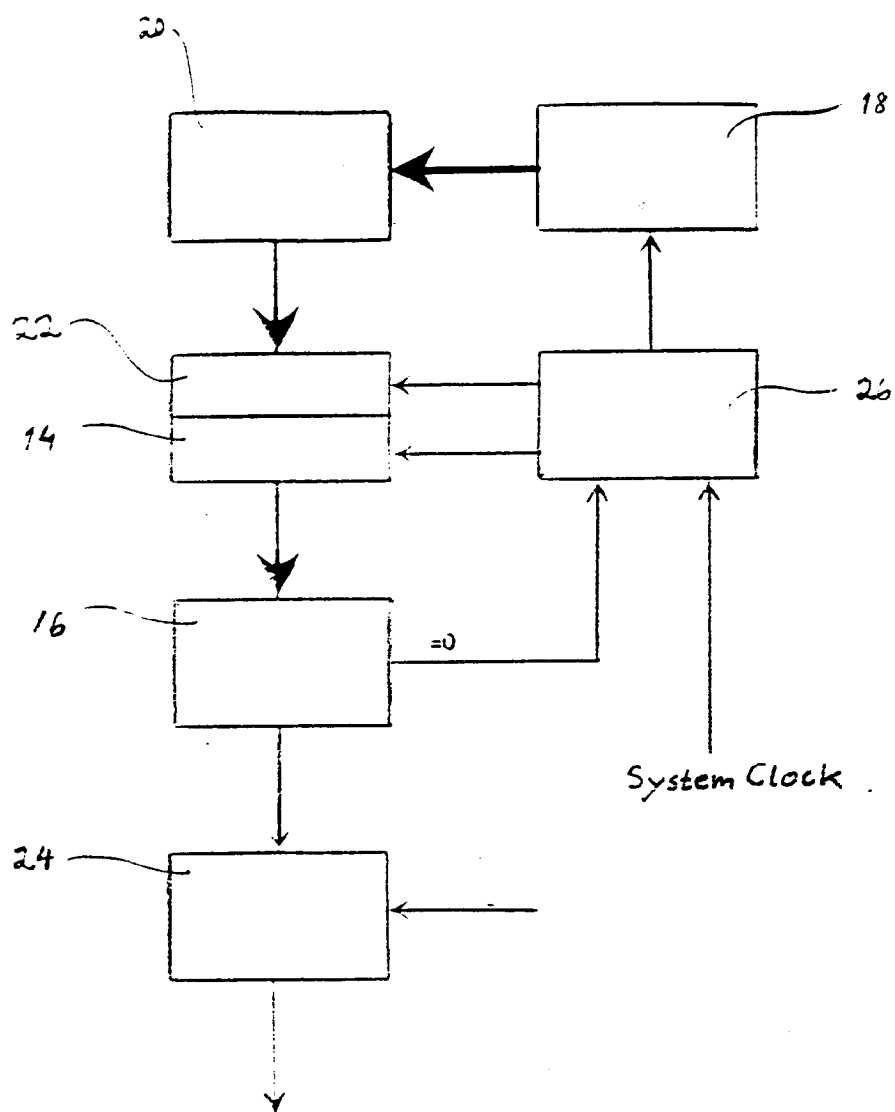


FIG 4



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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	EP, A2, 0420563 (ELI LILLY AND COMPANY), 3 April 1991 (03.04.91) * page 3, line 51 - page 4, line 10; page 5, line 36 - line 37 * --	1-19	A61N 1/39 A61N 1/365
A	US, A, 4735206 (CARL E. HEWSON), 5 April 1988 (05.04.88) * column 1, line 58 - column 2, line 16, claims 11-13 * --	1-19	
A	US, A, 5107834 (RAYMOND E. IDEKER ET AL), 28 April 1992 (28.04.92) * see whole document * --	1-19	
A	EP, A1, 0588125 (SIEMENS ELEMA AB), 23 March 1994 (23.03.94) * see whole document, cited in the application * --	1-19	TECHNICAL FIELDS SEARCHED (Int. Cl.6) A61N
A	EP, A1, 0588127 (SIEMENS ELEMA AB), 23 March 1994 (23.03.94) * see whole document, cited in the application * -----	1-19	
The present search report has been drawn up for all claims			
Place of search STOCKHOLM		Date of completion of the search 7 December 1995	Examiner THOMAS SKAGERSTEN
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